

DRAFT
Summary of Complaint for Injunction
(Based on Draft of 12/13/94)

Flue-Cured Tobacco Cooperative Stabilization Corporation & Philip Morris Inc.
versus
United States Food & Drug Administration and David A. Kessler, Commissioner

Plaintiffs: The Flue-Cured Tobacco Cooperative Stabilization Corporation is owned by and serves 180,000 tobacco growers and workers. Philip Morris is America's largest cigarette manufacturer.

Nature of Complaint: Action seeks review of FDA's assertion of jurisdiction over cigarettes which are sold in the normal manner, without any claim of therapeutic benefit and asks for a declaration that:

- FDA has no jurisdiction over such cigarette sales.
- FDA's assertion of jurisdiction is arbitrary, capricious and contrary to law.

The action further seeks an injunction:

- Requiring FDA to withdraw its assertion of jurisdiction.
- Prohibiting FDA from asserting jurisdiction, or initiating any rulemaking or enforcement.

Key arguments:

- If allowed to stand, FDA's assertion of jurisdiction would empower FDA to control all aspects of cigarette manufacturing and sales and to ban cigarette manufacturing and sales entirely.
- Congress has never granted FDA any jurisdiction over cigarettes for which no claims of therapeutic benefits are made.
- Congress has repeatedly rejected bills that would have given FDA such authority.
- Congress has established a program for federal regulation of cigarettes that precludes any role for the FDA.
- FDA has not and cannot establish that cigarettes are "drugs" as defined by the Federal Food, Drug and Cosmetic Act.

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- FDA's action directly contradicts its own longstanding conclusion that cigarettes sold in the normal way with no therapeutic claims are not drugs and that FDA has no power to regulate them.

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